

**REMARKS/ARGUMENTS**

Applicants submit the aforementioned amendments and following remarks in response to the Office Action mailed September 21, 2009.

Claims 1-21, 25 and 32 are pending in the instant application.

**Claim Rejections Under 35 U.S.C. § 103(a):**

The Examiner's previously rejected Claims 1-21, 24, 25 and 32 as being unpatentable over Choi et al., U.S. Patent No. 6,103,759 ("the '759 patent") in view of Olney, U.S. Patent No. 5,474,990 ("the '990 patent"). The Examiner has maintained the rejection of Claims 1-20, 25 and 32.

Applicants have now amended both independent method claims, i.e., claims 1 and 5, to exclude treatment of stroke induced hypoxia/ischemia.

Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. Section 103 (a)

**New Rejection Necessitated By Amendment Under 35 U.S.C. §103(a):**

The Examiner's previously rejected Claims 1-21, 24, 25 and 32 stand as being unpatentable over Choi et al., U.S. Patent No. 6,103,759 ("the '759 patent") in view of Zaidi et al., (*J Am Coll. Cardiol* 2000, Vol. 36(I), pages 181-184), ("the Zaidi/Cardiol article").

The Examiner states that Zaidi et al. teach that many patients with cardiovascular syncope, described as abnormal movements due to cerebral hypoxia experience convulsive blackouts. The Examiner contends that the instant invention would have been obvious to one of skill in the art at the time the invention was made since the convulsions and epilepsy accompany hypoxic-ischemic conditions and resulting injury and treatment with the instantly claimed compounds would also treat hypoxia-ischemia occurring due to convulsions.

The Applicants respectfully disagree. Cardiovascular syncope is caused by a reduction in blood supply to the brain due to a cardiac arrhythmia of some kind. A reduction of blood supply deprived the brain of both oxygen and glucose and rapidly causes dysfunction of neurons and will result in neuronal death if prolonged. The resulting convulsions which may occur are non specifically related to neuronal dysfunction and /or

death and the resulting disordered neuronal firing patterns. These convulsions could be treated with any effective anticonvulsant but that would not suggest that anticonvulsant was also effective in treating the damage caused by the cerebral hypoxia. Patients who are hypoglycemic also can have convulsions and any effective anticonvulsant may effectively treat such convulsions but this certainly does not suggest that this anticonvulsant is able to treat low blood sugar or the injury this can cause to the neurons. Convulsions are a final common result for many different kinds of injury or insult to the central nervous system and the ability of a compound to suppress the uncontrolled and disorganized discharge of neurons that characterize convulsions is unrelated to treatment of the underlying condition that may be the ultimate cause of the convulsions.

Thus, Applicants believe that the instant invention is not rendered obvious by U.S. Patent No. 6103759 (to Choi et al.) in view of Zaidi et al. and respectfully request that the Examiner withdraw the rejection under 35 U.S.C. 103(a).

**Modified Grounds Of Rejection Under 35 U.S.C. §112:**

The Examiner has rejected Claims 1-21, 24, 25 and 32 under 35 U.S.C. §112, first paragraph. The Examiner contends that, although the Examiner admits that the present specification demonstrates “treatment” of transient cerebral ischemia in the rat MCAO model by administration of the compound of Formula (Ib) S-enantiomer Applicants specification does not demonstrate “prevention” of neuronal cell death. And that demonstration of prevention of a disease in a mammal would require more extensive evidence to demonstrate possession.

Applicants respectfully disagree and suggest that the usual dichotomy between “treatment” and “prevention” as these terms relate to patentability is not at issue here. To demonstrate “prevention” of a disease generally requires different and perhaps more extensive evidence to enable as compared to “treatment” because prevention require the ability to predict ahead of time which individual will get a particular disease and by use of the invention be able to prevent the disease from occurring. However, in the case of neurodegenerative conditions the “treatment” is preventing neuronal cell death not anticipating and in a prophylactic manner preventing the disease condition from occurring in the first place. Applicants believe that the examples in the specification do show the

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prevention of neuronal cell death in the animal model and this constituted “treatment” of the disease not prevention of the disease.

Thus applicants submit that the Specification does enable “treatment” of neurodegenerative disorders and respectfully request that the Examiner withdraw the rejection under 35 U.S.C. 112 first paragraph.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

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Dated: 12/16/2009\_  
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Respectfully submitted,

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